CLAIMS

What is claimed is:

1. An isolated polynucleotide comprising 150 contiguous nucleotides of nucleotides 1 to 11,407 of SEQ ID NO:1 and having enhancer activity, wherein the 150 contiguous nucleotides are not depicted within SEQ ID NO:2 or SEQ ID NO:3.

2. The polynucleotide of claim 1, wherein said 150 contiguous nucleotides comprises nucleotides found within nucleotides about 5976 to about 9620 of SEQ ID NO:1.

3. The polynucleotide of claim 1, wherein said 150 contiguous nucleotides comprises nucleotides found within nucleotides about 6859 to about 8627 of SEQ ID NO:1.

4. The polynucleotide of claim 1, wherein said 150 contiguous nucleotides comprises nucleotides found within nucleotides about 7200 to about 8371 of SEQ ID NO:1.

5. The polynucleotide of claim 1, wherein said 150 contiguous nucleotides comprises nucleotides found within nucleotides about 8021 to about 8371 of SEQ ID NO:1.

6. An isolated polynucleotide comprising 150 contiguous nucleotides having at least about 70% sequence identity to a sequence within nucleotides 1 to 11,407 of SEQ ID NO:1, said polynucleotide having enhancer activity, wherein said 150 contiguous nucleotides are not depicted within SEQ ID NO:2 or SEQ ID NO:3.

7. An isolated polynucleotide comprising at least about 15 nucleotides which hybridize under stringent conditions to a polynucleotide comprising nucleotides 1 to 11,407 of SEQ ID NO:1, or a complement thereof, and wherein the at least about 15 nucleotides are not depicted within SEQ ID NO:2 or SEQ ID NO:3.

8. An isolated polynucleotide comprising nucleotides about 8021 to about 8371 of SEQ ID NO:1, wherein said polynucleotide has enhancer activity.

9. An isolated polynucleotide of claim 8, wherein the polynucleotide comprises nucleotides about 7200 to about 8371 of SEQ ID NO:1, wherein said polynucleotide has enhancer activity.

10. An isolated polynucleotide of claim 8, wherein the polynucleotide comprises nucleotides about 6859 to about 8627 of SEQ ID NO:1, wherein said polynucleotide has enhancer activity.

11. An isolated polynucleotide of claim 8, wherein the polynucleotide comprises nucleotides about 5976 to about 9620 of SEQ ID NO:1, wherein said polynucleotide has enhancer activity.

12. An isolated polynucleotide of claim 8, wherein the polynucleotide comprises nucleotides about 1 to about 9765 of SEQ ID NO:1, wherein said polynucleotide has enhancer activity.

13. An isolated polynucleotide of claim 8, wherein the polynucleotide comprises nucleotides about 1 to about 11,407 of SEQ ID NO:1, wherein said polynucleotide has enhancer activity.

14. An isolated polynucleotide comprising a transcriptional regulatory element, wherein said transcriptional regulatory element comprises a human glandular kallikrein (*hKLK2*) enhancer and a promoter.

15. The polynucleotide of claim 14, wherein the promoter is an *hKLK2* promoter.

16. The polynucleotide of claim 14, wherein the *hKLK2* enhancer comprises nucleotides about 8021 to about 8371 of SEQ ID NO:1.

17. The polynucleotide of claim 14, wherein the *hKLK2* enhancer comprises nucleotides of about 7200 to about 8371 SEQ ID NO:1.

18. The polynucleotide of claim 14, wherein the *hKLK2* enhancer comprises nucleotides of about 6859 to about 8627 SEQ ID NO:1.

19. The polynucleotide of claim 14, wherein the *hKLK2* enhancer comprises nucleotides about 5976 to about 9620 of SEQ ID NO:1.

20. The polynucleotide of claim 14, wherein the *hKLK2* enhancer comprises nucleotides about 1 to about 9765 of SEQ ID NO:1.

21. The polynucleotide of claim 14, wherein the *hKLK2* enhancer comprises nucleotides about 1 to about 11,407 of SEQ ID NO:1.

22. A polynucleotide vector comprising a human glandular kallikrein enhancer.

23. A vector according to claim 22, wherein the vector is a cloning vector.

24. A vector according to claim 22, wherein the vector is an expression vector.

25. A vector according to claim 23 comprising the polynucleotide of claim 1.

26. A vector according to claim 23 comprising the polynucleotide of claim 4.

27. A vector according to claim 24 comprising the polynucleotide of claim 1.

28. A vector according to claim 24 comprising the polynucleotide of claim 4.

29. A vector according to claim 24, wherein the vector is a viral vector.

30. A vector according to claim 22, wherein the vector is in a form selected from the group consisting of a liposome, a microparticle, a biocompatible polymer, a bacterium and a virus.

31. An adenovirus vector comprising an adenovirus gene under transcriptional control of a human glandular kallikrein transcription regulatory element (*hKLK2*-TRE).

32. The adenovirus vector of claim 31, wherein the adenovirus gene is a gene essential for adenoviral replication.

33. The adenovirus vector of claim 32, wherein the gene essential for replication is an adenoviral early gene.

34. The adenovirus vector of claim 33, wherein the adenovirus early gene is E1A.

35. The adenovirus vector of claim 34, wherein the adenovirus early gene is E1B.

36. The adenovirus vector of claim 31, wherein the *hKLK2*-TRE comprises an *hKLK2* promoter.

37. The adenoviral vector of claim 31, further comprising at least one additional adenoviral gene under transcriptional control of an *hKLK2*-TRE.

38. An adenovirus vector comprising a first gene under transcriptional control of a human glandular kallikrein (*hKLK2*) transcription regulatory element (*hKLK2*-TRE) and at least one other gene under transcriptional control of a prostate specific antigen (PSA) transcription regulatory element (PSA-TRE), wherein said *hKLK2*-TRE comprises an *hKLK2* enhancer and a promoter and wherein said PSA-TRE comprises a prostate specific enhancer (PSE) and a promoter.

39. The adenovirus vector of claim 38, wherein the first gene is essential for viral replication and a second gene is a heterologous polynucleotide.

40. The adenovirus vector of claim 38, wherein the first gene is a heterologous polynucleotide and a second gene is a gene essential for viral replication.

41. The adenovirus vector of claim 38, wherein first and second genes are heterologous polynucleotides.

42. The adenovirus vector of claim 38, wherein first and second genes are essential for viral replication.

43. The adenovirus vector of claim 42, wherein first and second genes are adenovirus early genes.

44. A composition comprising the polynucleotide of claim 1.

45. A composition comprising the polynucleotide of claim 4.

46. A composition comprising the vector of claim 22.

47. A composition comprising the adenovirus vector of claim 31.

48. A composition comprising the adenovirus vector of claim 38.

49. A host cell comprising the polynucleotide of claim 1.

50. A host cell comprising the polynucleotide of claim 4.

51. A host cell comprising the vector of claim 22.

52. A host cell comprising the adenoviral vector of claim 31.

53. A host cell comprising the adenoviral vector of claim 38.

54. A method for increasing transcription of an operably linked polynucleotide sequence in a cell comprising introducing a construct comprising a

human glandular kallikrein (*hKLK2*) enhancer and a promoter operably linked to said polynucleotide into a cell which allows said *hKLK2* enhancer to function.

55. The method of claim 54, wherein the *hKLK2* enhancer comprises nucleotides about 8021 to about 8371 of SEQ ID NO:1.

56. The method of claim 54, wherein the *hKLK2* enhancer comprises nucleotides about 7200 to about 8371 of SEQ ID NO:1.

57. The method of claim 54, wherein said operably linked polynucleotide sequence is a heterologous coding sequence.

58. The method of claim 57, wherein the heterologous coding sequence is a reporter gene.

59. The method of claim 58, wherein the reporter gene encodes an enzyme.

60. The method of claim 59, wherein the enzyme is luciferase.

61. The method of claim 57, wherein the heterologous coding sequence encodes a toxin.

62. The method of claim 57, wherein the heterologous coding sequence encodes a lymphokine.

63. A method for using the adenovirus vector of claim 31 comprising introducing said vector into a cell.

64. The method according to claim 63, wherein the cell is a mammalian cell.

65. The method according to claim 64, wherein the mammalian cell is a prostate cell.

66. A method for using the adenovirus vector of claim 38 comprising introducing said vector into a cell.

67. The method according to claim 66, wherein the cell is a mammalian cell.

68. The method according to claim 67, wherein the mammalian cell is a prostate cell.

69. A method for modifying the genotype of a target cell, said method comprising contacting the target cell with an adenovirus vector according to claim 31, wherein the vector enters the cell.

70. A method for modifying the genotype of a target cell, said method comprising contacting the target cell with an adenovirus vector according to claim 38, wherein the vector enters the cell.

71. A method for propagating an adenovirus specific for cells which allow an *hKLK2*-TRE to function, said method comprising combining an adenovirus vector of claim 31 with cells which allow function of an *hKLK2*-TRE, whereby said adenovirus is propagated.

72. A method for propagating an adenovirus specific for cells which allow an *hKLK2*-TRE to function, said method comprising combining an adenovirus vector of

claim 38 with cells which allow function of an *hKLK2*-TRE, whereby said adenovirus is propagated.

73. A method for conferring selective cytotoxicity on a cell which allows an *hKLK2* enhancer to function, comprising contacting the cell with an adenovirus vector of claim 31, wherein the adenovirus vector enters the cell.

74. A method for conferring selective cytotoxicity on a cell which allows an *hKLK2* enhancer to function, comprising contacting the cell with an adenovirus vector of claim 38, wherein the adenovirus vector enters the cell.

75. A method for screening compounds for the treatment of prostate cancer employing cells comprising an expression construct, said expression construct comprising an *hKLK2* transcriptional regulatory element (*hKLK2*-TRE) and a reporter gene whose expression product provides a detectable signal, wherein said *hKLK2*-TRE comprises an *hKLK2* enhancer and a promoter, and wherein said reporter gene is under the transcriptional control of said *hKLK2*-TRE, said method comprising the steps of:

b) combining said cells with a candidate compound in the presence of an appropriate inducing agent for a sufficient time for detectable expression of said reporter gene; and

c) detecting the level of expression of said reporter gene as compared to the level of expression in the absence of said candidate compound.

76. A method according to claim 75, wherein said expression product of said reported gene is an enzyme.

77. A method according to claim 76, wherein said enzyme is luciferase.

78. A method according to claim 77, wherein said detecting comprises: lysing said cells to obtain a lysate; and assaying said lysate for luminescence.

79. A method according to claim 75, wherein the *hKLK2* enhancer encompasses nucleotides about 7200 to about 8371 of SEQ ID NO:1 or active fragments thereof.

80. A method according to claim 75, wherein the *hLKL2* enhancer encompasses nucleotides about 8021 to about 8371 of SEQ ID NO:1 or active fragments thereof.

81. The method according to claim 75, wherein said cells are mammalian cells.

82. The method according to claim 75, wherein the mammalian cells are prostate cells containing an androgen receptor.

83. The method according to claim 75, wherein the promoter is an *hLKL2* promoter.